

### REMARKS/ARGUMENTS

Claims 1, 3-15 and 17-30 are pending in the present application. Claims 1, 3-15 and 17-30 were rejected in the Office Action. Claims 1, 3, 6-15 and 17-28 have been amended and new claims 32-38 have been added. No new matter has been added. Reexamination and reconsideration of the amended claim is respectfully requests.

#### Claim Rejections 35 U.S.C. § 102

Claims 1, 3-5, 7-15, 17-27 and 30 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,165,183 to Kuehn et al. (hereinafter referred to as Kuehn). Such rejection is overcome for the following reasons.

Claim 1 as amended now recites an interventional tool for repairing a cardiac valve of a patient having leaflets, said tool comprising:

a catheter having a shaft, a proximal portion and a distal portion adapted for placement through vasculature of the patient to a location near the cardiac valve; and

a capture device detachably connected to the catheter comprising at least two extendable distal elements and at least two extendable proximal elements, wherein the at least two extendable distal elements and the at least two extendable proximal elements are disposed near the distal portion of said shaft and held in a retracted position adjacent to the shaft, and

wherein the at least two extendable distal elements and the at least two extendable proximal elements are independently deployable and self-expand in an outward radial direction from the shaft to a deployed position further away from the shaft than the first position and to positions in between the retracted position and the deployed position, so as to capture the valve leaflets between the at least two extendable distal elements and the at least two extendable proximal elements. Support for this amendment may be found *inter alia* in Figs. 16A-16E, Figs. 20A-20B, and paragraphs 0094 and 0097 of the disclosure as filed, therefore no new matter has been added. Kuehn fails to disclose all of the claimed elements.

Kuehn discloses a valve leaflet fastener (Abstract) having gripper arms (Fig. 13B; col. 7, lines 50-54), a gripper/fastener applicator having arms (Fig. 14; col. 8, lines 12-15) and graspers/arms (Fig. 20; col. 9, lines 46-56). Kuehn also teaches that at least some of the gripper arms spring open and therefore are only in either the fully open or fully closed position, but not in positions in between fully open or fully closed. Therefore, Kuehn fails to teach or suggest an interventional tool for repairing a cardiac valve of a patient having leaflets wherein the at least two extendable distal elements and the at least two extendable proximal elements are independently deployable and self-expand in an outward radial direction from the shaft to a deployed position further away from the shaft than the first position and to positions in between the retracted position and the deployed position, so as to capture the valve leaflets between the at least two extendable distal elements and the at least two extendable proximal elements, as now required by amended claim 1.

Because a single cited reference fails to disclose each and every element of claim 1, anticipation under 35 U.S.C. § 102(e) cannot be established. Absent such as showing, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(e) rejection with respect to independent claim 1 and the dependent claims which depend therefrom.

Independent claim 18 has been similarly amended as claim 1 and therefore is also distinguishable from Kuehn for at least the reasons discussed above. Applicants respectfully request withdrawal of the 35 U.S.C. § 102(e) rejection with respect to independent claim 18 and the dependent claims depending therefrom.

Claims 1 and 6 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,206,907 to Marino et al. (hereinafter referred to as Marino). Such rejection is overcome for the following reasons.

As discussed above, claim 1 has been amended to recite in part a capture device detachably connected to the catheter comprising at least two extendable distal elements and at least two extendable proximal elements, wherein the at least two extendable distal elements and the at least two extendable proximal elements are disposed near the distal portion of said shaft and held in a retracted position adjacent to the shaft, and

wherein the at least two extendable distal elements and the at least two extendable proximal elements are independently deployable and self-expand in an outward radial direction from the shaft to a deployed position further away from the shaft than the first position and to positions in between the retracted position and the deployed position, so as to capture the valve leaflets between the at least two extendable distal elements and the at least two extendable proximal elements. Support for this amendment has been previously discussed. Marino fails to disclose all of the limitations of claim 1.

Marino discloses an occlusion device with stranded wire support arms for the closure of heart defects (Abstract). The stranded wire arms are heat treated and formed with a shape memory that expand during deployment (Abstract) and therefore are either in the fully open or fully closed position, but not in positions between fully open and fully closed. Marino also only discloses using his device for septal defects, patent foramen ovale and other vascular defects (Abstract) and therefore Marino also fails to disclose using his device to capture valve leaflets. Hence, Marino fails to teach or suggest that the at least two extendable distal elements and the at least two extendable proximal elements are independently deployable and self-expand in an outward radial direction from the shaft to a deployed position further away from the shaft than the first position and to positions in between the retracted position and the deployed position, so as to capture the valve leaflets between the at least two extendable distal elements and the at least two extendable proximal elements, as now required by amended claim 1.

Because a single cited reference fails to disclose each and every element of claim 1, anticipation under 35 U.S.C. § 102(e) cannot be established. Absent such as showing, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(e) rejection with respect to independent claim 1 and claim 6 which depends therefrom.

#### Claim Rejections 35 U.S.C. § 103

Claims 28 and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuehn. Claims 28 and 29 include the limitations of independent base claim 18 which has

been amended to recite a method of repairing a cardiac valve of a patient having leaflets, said method comprising:

providing an interventional tool comprising a catheter having a shaft, a proximal portion, a distal portion and a capture device detachably connected to the catheter, the capture device comprising at least two extendable distal elements and at least two extendable proximal elements wherein the at least two extendable distal elements and the at least two extendable proximal elements are disposed near the distal portion of said shaft and held in a retracted position adjacent to the shaft, and

advancing the distal portion through the vasculature to a location near the cardiac valve; and

deploying the at least two extendable distal elements and the at least two extendable proximal elements so the extendable proximal and distal elements self-expand either independently or together, in an outward radial direction from the shaft to a deployed position further away from the shaft than the retracted position or to positions therebetween so as to capture the valve leaflets; and

detaching the capture device from the interventional tool while said shaft is in the vasculature of the patient. Support for this amendment may be found *inter alia* in Figs. 16A-16E, Figs. 20A-20B, and paragraphs 0094 and 0097 of the disclosure as filed, therefore no new matter has been added.

As discussed above, Kuehn discloses a valve leaflet fastener (Abstract) with some arms that are only in either the fully open or fully closed position and not in positions therebetween. Therefore Kuehn fails to teach or suggest deploying the at least two extendable distal elements and the at least two extendable proximal elements so the extendable proximal and distal elements self-expand either independently or together, in an outward radial direction from the shaft to a deployed position further away from the shaft than the retracted position or to positions therebetween so as to capture the valve leaflets, as now required by claims 28 and 29.

Because the cited reference fails to teach or suggest all of the claim limitations, *prima facie* obviousness under 35 U.S.C. § 103 cannot be established. Absent such a showing,

Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of dependent claims 28 and 29.

New Claims

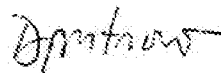
New claims 32-38 have been added. Support for these claims may be found in cancelled claims 16 and 31 as well as paragraphs 0089, 0094 and 0097 of the application as filed, therefore no new matter has been added. Claims 32-38 are believed to be patentable because they include the limitations of either independent claim 1 or 18, which have been distinguished from the cited references as discussed above.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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